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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,724

09/08/2003

Ian W. Hunter

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8905

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08/05/2008

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,724	<b>Applicant(s)</b> HUNTER, IAN W.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the second Office Action based on the 10/657724 application filed September 8, 2003. Claims 24-30 as amended are currently pending and considered below.

#### ***Response to Amendment***

1. In response to amendments and arguments made by applicant, the examiner hereby withdraws the objections to the specification, claims, and drawings. The examiner further withdraws the rejections under 35 U.S.C. 112 first and second paragraphs.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,354,273 to Hagen.

Hagen discloses a method for injecting drug into a biological body comprising: holding a drug (14) to be delivered to the body in a drug injector (12, Col. 4, lines 20-21); measuring a property of the skin (27, Col. 3, line 65-Col. 4, line 2; Col. 4, lines 55-57); adjusting the injection pressure of the drug injector with a servo-controller based on the skin property (27, 29, 34, 36, 37, 38, 42, 80—all of which work together in a

feedback (servo) mechanism; Col. 4, lines 40-43; Col. 7, lines 7-10); and injecting the drug into the body (Col. 4, line 49-52; Fig. 1, #22).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 24-26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hagen in view of USPN 6,132,385 to Vain.

Regarding claims 24-26, Hagen teaches a method for injecting drug into a biological body comprising: holding a drug (14) to be delivered to the body in a drug injector (12, Col. 4, lines 20-21); measuring the skin (27, Col. 3, line 65-Col. 4, line 2; Col. 4, lines 55-57); adjusting the injection pressure of the drug injector with a servo-controller based on the skin property (27, 29, 34, 36, 37, 38, 42, 80—all of which work together in a feedback (servo) mechanism; Col. 4, lines 40-43; Col. 7, lines 7-10); and

injecting the drug into the body (Col. 4, line 49-52; Fig. 1, #22). However, Hagen fails to teach that the skin measurement taken is the displacement of the skin after an applied force.

Vain discloses a method and device for recording oscillations of soft tissue in response to an applied force, which comprises a controller (8, 9) which drives a source probe (6) to stimulate a tissue wherein the displacement is detected and recorded (Col. 5, lines 19-24) and used to calculate various properties (which the examiner interprets includes compliance). The actuation of the probe has no pre-determined pattern and can therefore be considered a stochastic sequence of events. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Hagen and Vain before him or her to modify the measuring device of Hagen to include the source probe and driver of Vain because doing so would offer a more complete description of the skin's properties than just taking surface temperature. Therefore, it would have been obvious to combine Hagen with Vain to obtain the invention in the instant claims.

Regarding claims 28-30, Hagen discloses the method of claim 27 as disclosed above, but fails to teach or disclose the use of a stimulator and detector for determining skin displacement. Vain discloses these limitations as described above.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 24-30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763